UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

In Re Flint Water Cases	No. 5:16-cv-10444-JEL-MKM HON. JUDITH E. LEVY MAG. MONA K. MAJZOUB

CLASS PLAINTIFFS' MOTION FOR AN IMMEDIATE SUSPENSION OF THE USE OF PORTABLE XRF BONE SCANNING TESTS PENDING A FURTHER HEARING

Class Plaintiffs move for an order suspending the implementation of portable XRF bone scanning tests pending a hearing where the Court may review the regulatory authorization for the administration of such tests for the reasons set forth in the accompanying Memorandum Concerning the Use of Portable XRF Bone Scanning and in Support of Motion for an Immediate Suspension of its Use Pending a Further Hearing ("Memorandum").

Class Counsel has sought concurrence in this motion and reports as follows:

1. Defendant McLaren Hospital concurs in the relief sought;
2. Co-Liaison Counsel for the Individual Plaintiffs have not concurred;
3. The City of Flint takes no position on the relief sought; and
4. The State of Michigan takes no position on the relief sought.

For the reasons set forth in the accompanying Memorandum, Class Plaintiffs respectfully submit that this Court should issue an order notifying all counsel of record in these consolidated proceedings that the use of portable XRF bone scanning is immediately suspended, and that all counsel are instructed to suspend the administration of such tests by their agents, servants, employees or anyone in active concert or participation with them as part of the administration of the proposed Flint Water settlement. Class Plaintiffs respectfully request a hearing to further address these issues at the Court's earliest convenience.

Date: March 1, 2021

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CLASS PLAINTIFFS' MEMORANDUM CONCERNING THE USE OF PORTABLE XRF BONE SCANNING AND IN SUPPORT OF MOTION FOR AN IMMEDIATE SUSPENSION OF ITS USE PENDING A FURTHER HEARING

INTRODUCTION

In this Court's Opinion and Order Granting Plaintiffs' Motion to Establish Settlement Claim Procedures and Allocation for Preliminary Approval of Class Settlement Components and Granting Plaintiffs' Motion for an Order Adopting the Proposed Motion for Approval of Wrongful Death Settlement, ECF No. 1399 ("Preliminary Approval Order"), the Court addressed objections to the proposed partial Flint Water settlement presented by the *Chapman* objectors related to the issue of whether XRF bone scans were sufficiently available so as to include the utilization of such scans as one of many methods of determining eligibility for compensation in the settlement grid. *See,* ECF No. 1399, pp.59-61. At the preliminary approval hearing, Co-Lead Class Counsel (who, like the *Chapman* Plaintiffs, also had not used or obtained access to portable XRF bone scanning technology) indicated that they were exploring opportunities to secure such technology and make portable XRF bone scanning available on a more widespread basis. The Court recognized that "Co-lead Class Counsel are working to set up a bone scan program, which would render this issue moot." *Id*. at 61.

At the time Co-Lead Class Counsel made these representations to the Court, we understood that the use of portable XRF bone scanning technology on humans had obtained sufficient regulatory review and approval, such that there were no obstacles (other than obtaining access to the technology) to utilizing the technology in the course of settlement implementation in Flint. Based on Co-Liaison Counsel for the Individual Plaintiffs' advocacy for the use of portable XRF bone scanning technology throughout the settlement negotiation process, and indications from Co-Liaison Counsel that they and their experts had been using and were continuing to use portable XRF bone scanning devices to diagnose lead exposure in Flint residents, Class Counsel were at the time optimistic that a program could be implemented on a community-wide basis.

Interim Co-Lead Class Counsel submit this memorandum to further apprise the Court of their investigation of the use of portable XRF bone scanning technology for three reasons:

1. Co-Liaison Counsel and their experts have been unwilling or unable to provide any documentation confirming that the portable XRF bone scanning device they are using has been cleared by the United States Food and Drug Administration ("FDA") as safe and effective for use in diagnosing lead exposure in humans, or lawfully may be used for that purpose, and our ongoing investigation of the potential use and application of XRF technology reveals that portable XRF devices are not approved by the FDA – or any federal or state regulatory body – for use on humans;

2. The manufacturer of the portable XRF analyzer that is currently being employed in Flint for the administration of portable XRF bone scans has not applied for its registration by the FDA, consistent with Chapter 21 of the Code of Federal Regulations as a "medical device" that may be used on humans; and the manufacturer's user manual suggests just the contrary-that the device is not intended for use on humans; and

3. Since the safety of this radiation emitting device has not been evaluated in an FDA regulatory review, Interim Co-Lead Class Counsel cannot currently endorse its use, and therefore request that the Court **order an immediate suspension of the administration of portable XRF tests** unless and until the regulatory authorization and safety of such tests have been confirmed.

We also respectfully submit that the Court convene a hearing to review these issues at the earliest possible date.

II. USE OF PORTABLE XRF TECHNOLOGY FOR EVALUATING LEAD CONTENT IN BONE CONSTITUTES THE USE OF A RADIOLOGY DEVICE ON HUMANS, REQUIRING REVIEW AND APPROVAL BY THE FDA.

The Amended Settlement Agreement's Required Proofs Grid (Ex. 8, Dkt. 1319-2) provides that Category 1 claimants—Minor Children, Ages 6 and Younger, lead level—may receive a 2x monetary award if they submit either a Blood Lead Test taken between May 16, 2014 and August 31, 2016, or else a "Bone Lead Test." Ex. 8 at 2-3. The Grid describes the available Bone Lead Test as follows:

> **Bone Lead Test:** Test with an X-Ray fluorescence (XRF) device optimized to measure bone lead in vivo in humans and to perform measurements of in vivo bone lead in bones. Test must have been taken between May 16, 2014 and 90 days after the date of the Preliminary Approval Order, except that the end date of 90 days after the date of the Preliminary Approval Order shall not be applied to Future Minor Claimants, who shall not be subject to that end date restriction. XRF bone test results must be signed and verified as properly calibrated,

> reliable and accurate by a board-certified Ph. D and/or M.D. qualified to do so in the appropriate fields of study.

Id. at 3. The Settlement Grid thus gives Category 1 claimants a monetary incentive to obtain bone-lead testing if they did not previously receive the referenced blood-lead testing between 2014 and 2016. Similar use of the XRF technology is contemplated in other portions of the grid. [1]

The portable XRF device currently being employed in the City of Flint – under protocols developed by Individual Plaintiffs' expert physicist Aaron Specht, Ph. D is the Niton XL3t GOLDD+ Analyzer. Class Counsel sought access to attend the Specht deposition to obtain scientific information and details regarding the use of portable bone scan technology. In response to the request Individual Plaintiffs moved for a protective order to prevent such access, which was granted by the Court.[2] ECF No. 1283 and 1285. At a subsequent hearing, the Court also ordered that copies of the transcript of the Specht deposition transcript which Class Plaintiffs

[1] The Grid likewise gives monetary incentives for Category 2-4 minor children, Category 8-11 minor adolescents, Category 15-18 minor teens, and Category 22-23 and 25 adults to obtain bone-lead testing. *See id.* at 3-33.

[2] Mr. Pitt argued at the October 2, 2020 protective order hearing that Class Plaintiffs needed access to "(n)ot only the technology, but how he (Dr. Specht) has developed the protocols, the standard operating procedures, the test results, global test results for Flint children, global test results in general, how he calibrates his equipment, how he has established various cutoff scores to determine if there's actual lead in the phone (sic), things of that nature." ECF No. 1285, October 2, 2020 Hearing Transcript, p.17. The Court granted Individual Plaintiff's Motion for Protective Order and precluded Class Plaintiffs' participation in the deposition. ECF No. 1283.

had received must be destroyed.[3] This precluded Class Plaintiffs' ability to obtain crucial information regarding the portable XRF device.

The user manuals relating to the Niton XL3t GOLDD+ Analyzer ("XL3t") make clear that the device was intended for use in identifying the lead content in inanimate objects and ***was never intended for use in evaluating humans.*** The user manual provides:

- "**CAUTION** Niton analyzers are not intrinsically safe analyzers. All pertinent Hot Work procedures should be followed in areas of concern."
- "**WARNING** Always treat radiation with respect. Do not hold your analyzer near the measurement window during testing. **Never point your analyzer at yourself or anyone else when the shutter is open."**
- "Reasonable effort should be made to maintain exposures to radiation as far below dose limits as is practical."
- "The closer you are to a source of radiation, the more radiation strikes you."
- "**Remember to keep your hands and all body parts away from the front end of the analyzer when the shutter is open to minimize your exposure."**
- "**Note NEVER OPERATE THE DEVICE WITH A PART OF YOUR BODY DIRECTLY IN THE PRIMARY BEAM PATH OR WITH THE PRIMARY BEAM PATH DIRECTED AT ANYONE ELSE."**

[3] At the October 21, 2020 hearing regarding access to the deposition transcripts, Mr. Pitt argued "The technology is what we're interested in knowing about… the technology has very broad implications across the community…So we need to know more about that technology because it is unique and it is probably proprietary."

- "The Niton XL3t analyzer is designed to be safe to operate provided that it is used in accordance with manufacturer's instructions."

- "**Avoid holding the front of the analyzer when the x-ray tube is energized and the shutter is open. Never point the instrument at yourself or anyone else when the shutter is open and the x-ray tube is energized. Never look into the path of the primary beam."**

- "**As mentioned many times in this chapter, never place any part of your body in the path of the x-ray beam."**

Ex. 1 (Thermo Fisher Scientific Niton Analyzers, XL3 Analyzer, Version 7.0.1 User's Guide, Revision C, November 2010) (emphasis added) at pp. 3-4, 7, 10-11.

The fact that the manufacturer of the portable XRF XL3t has not envisioned its use in human applications has significant regulatory consequences. Typically, these handheld analyzers are used extensively by scrap metal recyclers to identify the metal and alloys in a scrapyard, including identifying the existence of contaminants or hazardous elements. (They are also used in other industries, including manufacturing, mining, oil and gas operations, etc.) When used in a manner ***other than*** for medical or diagnostic purposes, manufacturers of electronic products that emit x-ray or particulate radiation are responsible for compliance with all applicable requirements, including the Electronic Production Radiation Control Act.[4]

[4] *See*, FDA website (https://www.fda.gov/radiation-emitting-products/home-business-and-entertainment-products/x-ray-particulate-products-other-medical-diagnostic-or-cabinet citing 21 U.S.C.A. § 360ii)

Indeed, the Court has already addressed the use of portable XRF testing related to inanimate objects in the context of property inspection protocols developed in this case. There, the following precautions were adopted by the Court:

> The consultants and investigators **will wear radiation dosimeters to measure their radiation exposure**, although exposures are generally extremely low if the XRF instruments are used in accordance with the manufacturer's instructions. **If feasible, persons should not be near the other side of a wall, floor, ceiling, or other surface being tested. The shutter of an XRF should never be pointed at anyone, even if the shutter is closed**.

See, Third Amended Case Management Order, Exhibit E, Home Inspection Protocol, ECF No. 1131-5.

But when products like the portable XRF XL3t are used for medical applications ***in humans*** (*e.g*, as here, in diagnosing the extent of lead exposure in potential beneficiaries of the settlement), they meet the definition of a "device" under the Food, Drug, and Cosmetic Act ("FDCA") because they are "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease…" 21 U.S.C. §321(h)(1)(B).[5] Consequently, if

[5] The FDA states: "Most radiation-emitting products are not considered to be medical devices. However, if you make any medical claims, your product is a medical device also subject to the provisions of the FD&C Act for medical devices in addition to the provisions for radiation emitting products." *See*, https://www.fda.gov/medical-devices/classify-your-medical-device/does-product-emit-radiation

used on humans, such devices must also comply with the medical device regulations, set forth in Chapter 21 of the Code of Federal Regulations. Medical devices are categorized into one of three classes (I, II, or III), based on the degree of risk they present. As device class increases from class I to class II to class III, the regulatory controls also increase, with class I devices subject to the least regulatory control, and class III devices subject to the most stringent regulatory control. The classes of devices, regulatory controls and submission types are summarized in this table:

Class	**Risk**	**Potential Harm**	**Regulatory Controls**	**Submission Type or Exemption**
I	Lowest	Present minimal potential for harm	General	510(k) 510(k) Exempt
II	Moderate	Higher risk than class I devices	General and Special (if available)	510(k) 510(k) Exempt
III	Highest	Highest Sustain or support life, are implanted, or present potential unreasonable risk of illness or injury	General and PMA	Pre-Market Authorization

If portable XRF devices were to be used for human purposes, they would likely be designated as a Class II medical device as other devices that use x-ray technologies or emit radiation in clinical settings are classified as Class II. Examples include: Bone densitometer (21 CFR 892.1170), Stationary x-ray system (21 CFR 892.1680), Mammographic x-ray system (21 CFR 892.1710), and Mobile x-ray system (21 CFR 892.1720).

In order to market the portable XRF XL3t device as a medical device suitable for treatment of humans, the manufacturer of the device must obtain clearance via 510(k) or the 510(k)exemption process, 21 U.S.C. §360(k). Class Counsel have conducted a review of the FDA's database for 510(k) submissions and approvals for the portable XRF XL3t and have not found that the device has a pending submission – much less a clearance. Additionally, although some radiology devices have received blanket exemptions from FDA review,[6] portable XRF devices do not appear to fall into this category.[7]

Use of an unapproved portable XRF XL3t in a human setting involving children – without FDA review of the safety of the device or determination that it is

[6]https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm?GMPPart=892#start

[7] It is conceivable that the individuals performing portable XRF XL3t bone scans in Flint have obtained permission to use the device on children under an investigational device exemption from the FDA pursuant to 21 U.S.C.§360(g). *See,* https://www.fda.gov/medical-devices/investigational-device-exemption-ide/ide-approval-process. But such an exemption is subject to several regulatory requirements, including the "Informed Consent of Human Subjects" requirements in 21 CFR Subpart B §50.20 *et. seq.* Class Plaintiffs have requested verification from Counsel for Individual Plaintiffs of the regulatory authorization and safety protocols for their use of the portable XL3t device. Such verification and protocols have not been forthcoming. It is also not clear whether any informed consent procedures have been implemented.

exempt from a 510(k) review process[8] – is particularly unsettling. FDA Guidance concerning the use of x-ray imaging in children notes that:

> X-ray exams should be performed for children *only* when the child's physician believes they are necessary to answer the clinical question or to guide treatment. Medical imaging professionals should use techniques that are adjusted to administer the lowest radiation dose that yields an image quality adequate for diagnosis or intervention (i.e., radiation doses should be "As Low as Reasonably Achievable").[9] (emphasis added)

The only human testing in a study for a portable XRF XL3t device that has ever been performed in the United States, of which Co-Lead Class Counsel are aware, was performed in adults – not children.[10]

Moreover, the United States Centers for Disease Control specifically does NOT recommend the use of X-ray fluorescence of long bones for children at any blood lead level.[11]

Class Plaintiffs have continued to attempt to obtain evidence of such regulatory approvals, or waivers, from the manufacturer of the portable XRF XL3t

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[8] To obtain clearance of 510(k) devices, the manufacturer must show they are substantially equivalent to devices that received regulatory authority to be used in humans. That has not occurred with the XRF XL3t.

[9] https://www.fda.gov/radiation-emitting-products/medical-imaging/pediatric-x-ray-imaging

[10] See, *Zhang, Specht, et. al.*, "Evaluation of a portable XRF device for *in vivo* quantification of lead in bone among a U.S. population" Sci Total Environ. 753 (2021) 142351."We measured bone Pb concentrations in vivo using portable XRF and KXRF, each measured at the mid-tibia bone in 71 people, 38-95 years of age."

[11] https://www.cdc.gov/nceh/lead/advisory/acclpp/actions-blls.htm

device and learned, to the contrary, that the manufacturer ***refuses*** to sell the device to purchasers who intend to use it for human applications. Class Counsel has further explored use of the device with a team of researchers at the University of Michigan, but learned that the University will not participate in such a program until the regulatory issues outlined in this Memorandum are addressed.

Irrespective of whether Defendants (or the manufacturer of any portable XRF device) sets forth evidence or testimony that portable XRF testing is safe and effective for use in children, absent regulatory clearance or waiver, it is not a determination for a Court to make; such a determination is solely within the purview of the FDA. The United States District Court for the Southern District of Florida recognized the FDA's authority in making such determination. *In U.S. v. Sene X Eleemosynary Corp., Inc.*, the United States sought injunctive relief against defendants who promoted and sold a drug that was not approved by the FDA, and the court set forth:

> Although there was testimony that GH-3 is harmless, that is not a determination which, under the Act [Food Drug & Cosmetic Act], the Court should, or will, make; that is a determination to be made upon proper application to the FDA. Likewise, with respect to GH-3's efficacy, the Court should not, and will not, undertake to decide whether GH-3 is effective for any one of the twenty or more uses for which the product is promoted or intended. Again, that is not a determination for the Court to make; rather, it is a determination to be resolved on the basis of scientific evidence and testing in a new drug application filed with the FDA.

United States v. Sene X Eleemosynary Corp., 479 F. Supp. 970, 977–78 (S.D. Fla. 1979) (*citing Weinberger v. Bentex Pharmaceuticals*, 412 U.S. 645, 652, 93 S.Ct. 2488, 37 L.Ed.2d 235 (1973); *United States v. An Article of Drug . . . X-OTAG TABLETS*, 441 F.Supp. 105, 109 (D.Colo.1977), Aff'd 602 F.2d 1387 (10th Cir. 1979)). Although these court rulings issued in the context of FDA evaluations of drugs, a similar rationale applies to medical devices. Without FDA review and clearance, it would be inappropriate for this Court to make a determination, or tacitly endorse the use of portable XRF devices as safe for use in humans, and specifically children. [12]

At this juncture, Class Plaintiffs request that until the Court can address the issues set forth in this Memorandum, ***the Court should stop all portable XRF testing.*** Class Plaintiffs believe we have an obligation to bring to the Court's attention the fact that the portable XRF XL3t has not been FDA cleared for use on humans, much less children, as a medical device, and that the Court must determine,

[12] The Federal Food, Drug, and Cosmetic Act "rests upon the constitutional power resident in Congress to regulate interstate commerce. Article 1, s 8, cl. 3. To the end that the public health and safety might be advanced, it seeks to keep interstate channels free from deleterious, adulterated and misbranded articles of the specified types." *United States v. Walsh*, 331 U.S. 432, 434, 67 S. Ct. 1283, 1284, 91 L. Ed. 1585 (1947) (internal citations omitted). *See also United States v. Sullivan*, 332 U.S. 689, 696, 68 S. Ct. 331, 335–36, 92 L. Ed. 297 (1948) (The purpose of the Act is "to safeguard the consumer by applying the Act to articles from the moment of their introduction into interstate commerce all the way to the moment of their delivery to the ultimate consumer).

before the administrations of thousands of additional tests, whether such tests are legally permissible based on findings of safety and efficacy made by a regulatory agency with the requisite authority.

Finally, in this Memorandum, Class Plaintiffs are not addressing whether the use of XRF bone scanning as a method of determining compensation is an *appropriate* consideration for inclusion in the settlement grid. Rather, the more pressing question is whether implementation of portable XRF bone scanning is even *permissible.* Class Plaintiffs respectfully submit that neither we, other Plaintiffs' lawyers, the Special Master nor this Court are qualified to make a determination, absent appropriate FDA documentation, as to whether this device is cleared for use in humans, and especially children. Indeed, Congress has delegated that decisional authority exclusively to the U.S. Food and Drug Administration under the Food, Drug, and Cosmetic Act. Respectfully, the initial decision as to whether the portable Niton XRF XL3t GOLDD+ Analyzer is safe and effective, and thus permissible for use in human subjects (and especially children) such that it may be included as a basis for evaluation in a settlement in this case is in the hands of the FDA.[13]

[13] It is also unclear as to whether the repeated administration of portable XRF tests on multiple human subjects in a clinical setting would require licensure under Michigan state requirements concerning the use of radiological devices. Since it is a threshold issue as to whether use of the devices is permissible at all, this Memorandum does not address those additional regulatory issues.

CONCLUSION

For the foregoing reasons, Class Plaintiffs respectfully submit that this Court should issue an order notifying all counsel of record in these consolidated proceedings that the use of portable XRF bone scanning is immediately suspended, and that all counsel are instructed to suspend the administration of such tests by their agents, servants, employees or anyone in active concert or participation with them as part of the administration of the proposed Flint Water settlement. Class Plaintiffs respectfully request a hearing to further address these issues at the Court's earliest convenience.

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CERTIFICATE OF SERVICE

I hereby certify that on March 1, 2021, I caused **Class Plaintiffs' Motion For an Immediate Suspension of the Use of XRF Bone Scanning Tests Pending a Further Hearing and Memorandum In Support** to be electronically filed with the Clerk of the Court using the Court's electronic submission system. Notice of the filing was sent to all parties by operation of the Court's electronic filing system. I declare the above statement is true and to the best of my knowledge, information and belief.

Dated: March 1, 2021 */s/ Paul F. Novak*